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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,853	11/17/2000	Ashvin H. Desai	10284-0269451	8968

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EXAMINER	
FERKO, KATHRYN P	
ART UNIT	PAPER NUMBER
3743	8

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,853	DESAI, ASHVIN H.	
	Examiner	Art Unit	
	Kathryn Ferko	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: element 20. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: on page 7, line 3 the needle is referenced as element 7c. There does not appear to be a corresponding element 7c in the drawings. Perhaps, there is a typographical error. Further on page 7, element 80 is labeled as probe as well as catheter, in line 27. Also, on page 8, in line 17, needle is referenced as element 18. It appears that bladder is element 18. Perhaps, it was intended to reference needle as element 108.

Appropriate correction is required for these and any other inconsistencies within the specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 5, 6, 9-12, 15, 16, 20-22, 24-26, 27, 30, 31, 33, 34, 36, 38, 39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al. in US Patent No. 5,472,441.

Regarding claims 1, 2, 9,10,15,21,24,15,30,33,36, and 41, Edwards et al. discloses a method for treating a localized portion of body tissue via inserting a needle apparatus in a body, the apparatus including at least one hollow needle core for delivering a treatment substance into the body, as recited in column 7, lines 45-55, column 8, lines 55-65, column 10, lines 1-15, column 13, column 16, and column 18, lines 5-13; guiding the needle apparatus to a target tissue in need of treatment, where the guiding includes use of an imaging technique for viewing inside an area of tissue, as recited in column 6, lines 55-65 and column 7, lines 50-55; applying the treatment substance to the target tissue through the needle apparatus, wherein the treatment substance includes a component selected from the group of tissue necrosis agents, genes, viruses, proteins, inhibitors, tissue markers, bioabsorbable polymers and other biological agents and chemotherapeutic agents, as recited in column 8, line 57 and column 11, lines 5-52; causing selective tissue necrosis, as recited in column 11, line 61; a treatment substance that is in the form of microspheres, as recited in column 16, lines 29-67; applying RF energy to the target tissue through an RF electrode, as recited in column 9, lines 60-65; a substance that includes an electrically conductive component; as recited in column 16, line 16; a substance with an imaging contrasting agent, as recited in column 17, lines 1-4; a target tissue that

Claim 4

is in a prostate and wherein the method is for treating a condition selected from the group of BPH and prostate cancer and is accomplished by a method selected from the group of Transrectal, Transurethral and Transperineal approach, as recited in column 6, lines 60-63 and 08/148,441 which is incorporated by reference in column 1, line 11 (a copy has been provided); the method applied for treatment of a body part selected from the group of prostate, liver, uterus, bladder, kidney, lung and breast; as recited in column 4, line 14; inserting that is accomplished using an approach selected form the group of percutaneous, laparoscopic, and endoscopic, as recited in column 6, lines 55-65; guiding that is further performed using a device selected from the group of biopsy apparatus, laparoscope, endoscope, hysteroscope, MRI, CT scan, and ultrasound imaging apparatus, as recited in column 6, lines 55-65; inserting that is performed by at least one method selected from the group of percutaneous, through incision, and through a natural body opening, and a laparoscopic approach, as stated throughout; microspheres that further include a chemo agent selected from the group of hypertonic saline solution, ethanol, acetic acid, and other necrosing agents, as recited in column 11, column 16, lines 65-67 and column 17, lines 1-5; and a conductive substance that is selected from the group of conductive polymers, conductive agents, conductive elements, carbon particles, and metallic suspensions, as recited in column 16, line 16.

With regard to claims 5, 6, 11, 12, 16, 20, 22, 26, 27, 31, 34, 38, and 39, Edwards et al. disclose a method for treating a localized portion of the body

tissue via inserting a needle apparatus in a body, the apparatus including at least one hollow core needle for delivering a treatment substance into the body; guiding the needle apparatus to a target tissue in need of treatment, as recited in column 7, lines 44-55, column 8, lines 55-65, column 10, lines 1-15, column 13, column 16 and column 18-5-13; applying the treatment substance to the target tissue through the needle apparatus, wherein the treatment substance includes a plurality of microspheres including a component selected from the group consisting of tissue necrosing agents, genes, viruses, proteins, inhibitors, tissue markers, bioabsorbable polymers and other biological agents and chemotherapeutic agents, as recited in column 16, lines 29-67 and column 11, lines 5-52; causing selective tissue necrosis, as recited in column 11, line 61; applying RF energy to the target tissue through an RF electrode, as recited in column 9, lines 60-67; microspheres that include an electrically conductive agent, as recited in column 16, line 16 and column 16, lines 35-40 (wherein conductive fluid can be considered a therapeutic substance); guiding that includes use of an imaging technique, as recited in column 6, lines 55-66 and column 7, lines 50-55; microspheres that include a contrasting agent, as recited in column 17, lines 1-4; each microsphere that has a container holding a gas and a substance selected from the group consisting of a gel and a liquid for providing image enhancement when the imaging technique is ultrasound, as recited in column 16 and column 17, lines 1-5; a target tissue that is in a prostate and wherein the method is for treating a condition selected from the group of BPH and prostate cancer and is

accomplished by a method selected from the group of Transrectal, Transurethral and Transperineal approach, as recited in column 6, lines 60-63 and 08/148,441 which is incorporated by reference in column 1, line 11 (a copy has been provided); the method is applied for treatment of a body part selected from the group of prostate, liver, uterus, bladder, kidney, lung and breast, as recited in column 4, line14; inserting that is accomplished using an approach selected form the group of percutaneous, laparoscopic, and endoscopic, as recited in column 6, lines 55-65; guiding that is further performed using a device selected from the group of biopsy apparatus, laparoscope, endoscope, hysteroscope, MRI, CT scan, and ultrasound imaging apparatus, as recited in column 6, lines 55-65; inserting that is performed by at least one method selected from the group of percutaneous, through incision, and through a natural body opening, and a laparoscopic approach, as stated throughout; microspheres that have a gas (some air inclusion is inherent); and a gas that is selected form the group of air, helium, fluorocarbon, and carbon dioxide.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3, 8, 13, 14, 18, 19, 23, 28, 29, 32, 35, 37, and 40 rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. in US Patent No. 5,472,441 in view of Barker et al. in JP 405078237.

Edwards et al. discloses a method for treating a localized portion of a body tissue via inserting a needle apparatus in a body, where the apparatus has at least one hollow core for delivering a treatment into the body, as recited in column 7, lines 44-55, column 8, lines 55-65, column 10, lines 1-15, column 13, column 16, and column 18, lines 5-13; guiding the needle apparatus to a target tissue in need of treatment; applying the treatment to the target through the needle apparatus, wherein the treatment includes at least one component selected from the group consisting of tissue necrosing agents, genes, viruses, proteins, inhibitors, tissue markers, bioabsorbable polymers and other biological agents and chemotherapeutic agents, as recited in column 11, lines 5-52; causing selective tissue necrosis, as recited in column 11, line 61; applying RF energy to the target tissue through an RF electrode, as recited in column 9, lines 60-65; an electrically conductive agent, as recited in column 16, line 16; guiding that includes use of an imaging technique, as recited in column 6, lines 55-66 and column 7, lines 50-55; an image contrasting technique, as recited in column 17, lines 1-4; a target tissue that is in a prostate and wherein the method is for treating a condition selected from the group of BPH and prostate cancer and is accomplished by a method selected from the group of Transrectal, Transurethral and Transperineal approach, as recited in column 6, lines 60-63 and 08/148,441

which is incorporated by reference in column 1, line 11 (a copy has been provided); the method is applied for treatment of a body part selected from the group of prostate, liver, uterus, bladder, kidney, lung and breast, as recited in column 4, line 14; inserting that is accomplished using an approach selected form the group of percutaneous, laparoscopic, and endoscopic, as recited in column 6, lines 55-65; guiding that is further performed using a device selected from the group of biopsy apparatus, laparoscope, endoscope, hysteroscope, MRI, CT scan, and ultrasound imaging apparatus, as recited in column 6, lines 55-65; inserting that is performed by at least one method selected from the group of percutaneous, through incision, and through a natural body opening, and a laparoscopic approach; as recited in column 6, lines 55-65; and a chemo agent selected from the group of hypertonic saline solution, acetic acid, ethanol and other tissue necrosing agents, as recited in column 11, lines 5-52.

However, Edwards et al. do not explicitly recite a treatment substance that is in the form of a gel and a gel wherein the gel further has a binding agent and that binding agent is selected form the group of biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil. On the other hand, Barker et al. teach a treatment substance that is in the form of a gel and a gel wherein the gel further has a binding agent and that binding agent is selected form the group of biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil, as stated in the purpose and constitution.

Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Edwards et al. to use a gel for the purpose of increasing viscosity allowing more controlled delivery.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,461,296 in view of Barker et al. in JP 405078237 and further in view of Unger et al. in US Patent No. 5,542,935.

Although the conflicting claims are not identical, the claims of the current application are broader in some respects and more specific in others. The claims of U.S. Patent No. 6,461,296 do not recite a treatment that is a gel and a treatment that is a microsphere. On the other hand, Barker et al. teach a treatment substance that is in the form of a gel and a gel wherein the gel further has a binding agent and that binding agent is selected form the group of

biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil, as stated in the purpose and constitution.

Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of to use a gel for the purpose of increasing viscosity allowing more controlled delivery. Furthermore, Unger et al. teach of therapeutic drug delivery via microspheres, as stated in the abstract. Therefore, it would also be obvious to incorporate microspheres for the purpose of timed/controlled release.

9. Claims 1-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,231,591 in view of Unger et al. in US Patent No. 5,542,935.

Although the conflicting claims are not identical, the claims of the current application are broader in some respects and more specific in others. The claims of U.S. Patent No. 6,461,296 do not recite a treatment that is a microsphere. On the other hand, Unger et al. teach of therapeutic drug delivery via microspheres, as stated in the abstract. Therefore, it would also be obvious to incorporate microspheres for the purpose of timed/controlled release.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2003/0009153; US 2002/0177772; US 2002/0051749; US 2002/0026127; US 2002/0002349; US Patent No. 6,514,193; US

Patent No. 6,332,089; US Patent No. 6,322,536; US Patent No. 6,306,132; US Patent No. 6,227,112.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF
April 3, 2003

Henry Bennett
Supervisory Patent Examiner
Group 3700